

EXHIBIT 31

Strom

Page 159

1 IN THE UNITED STATES DISRICT COURT

2 IN THE DISTRICT OF NEW JERSEY

3 -----x
4 CHAYA GROSSBAUM and MENCHEN

5 GROSSBAUM, Her Spouse, Individually

6 and as Guardian ad litem of the

7 infant, ROSIE GROSSBAUM,

8 Plaintiffs,

9 -against-

10 GENESIS GENETICS INSTITUTE, LLC, et al

11 THE STATE OF MICHIGAN, MARK R. ...

12 HUGHES, M.D., NEW YORK UNIVERSITY

13 SCHOOL OF MEDICINE and NEW YORK

14 UNIVERSITY HOSPITALS CENTER, both

15 corporations of the State of New York,

16 ABC CORPORATIONS, et al and John Doe

17 DOE,

18 Defendants.

19 -----x

20 DEPOSITION OF CHARLES STROM

21 New York, New York

22 June 24, 2010

23
24 Reported by:

25 Judith A. Frost

Job No. NJ263710

Index No.

07-CV-359

Strom

<p style="text-align: right;">Page 176</p> <p>1 percentage is minimal. It's a significant risk. It 2 may be small, but not minimal.</p> <p>3 Q May I respectfully suggest that it is 4 a little bit of an disingenuous answer in the sense 5 that, if I follow your argument, that if you enter 6 an intersection on a green light it carries it with 7 some small chance that someone will run a red light 8 and kill you.</p> <p>9 MR. STEIN: Not one in 200, more like 10 one in 200,000. Forgive me for 11 interrupting, Dr. Strom.</p> <p>12 MR. LEUCHTMAN: It is not Dr. Strom's 13 forgiveness that you need.</p> <p>14 MR. STEIN: Well, I have to forgive 15 the witness for being imposed upon.</p> <p>16 Dr. Strom is not arguing, so when you 17 characterize his testimony as argument it is 18 inappropriate.</p> <p>19 Secondly, when you begin to challenge 20 his answers with argument, that's 21 inappropriate in a deposition. Please 22 conduct your deposition by asking questions 23 and getting information and not arguing with 24 the witness and not characterizing his 25 testimony in the fashion which you have.</p>	<p style="text-align: right;">Page 178</p> <p>1 increased risk due to miscarriage of CVS of 2 approximately one to two percent, and that's 3 statistically significant.</p> <p>4 Q It's a one-half of one percent chance 5 of miscarrying in amniocentesis?</p> <p>6 A That's the common reported, yes.</p> <p>7 Q Can allele dropout occur even when the 8 utmost care has been exercised?</p> <p>9 A Yes.</p> <p>10 Q Is that true in single cell testing?</p> <p>11 A Yes.</p> <p>12 Q Is it true in multiplex testing or 13 also using genetic markers?</p> <p>14 A Yes.</p> <p>15 Q Is it your opinion that allele dropout 16 is a likely cause of failure of misdiagnosis in this 17 case?</p> <p>18 A Yes.</p> <p>19 Q Can allele dropout take place 20 concurrently with other possible causes which we 21 discussed previously?</p> <p>22 A Yes.</p> <p>23 Q Have you read literature about the 24 role of unprotected sex and the failure or 25 misdiagnosis in PGD?</p>
<p style="text-align: right;">Page 177</p> <p>1 MR. LEUCHTMAN: I think we both 2 understand each other.</p> <p>3 Q What does the term statistical 4 significance mean to you?</p> <p>5 A Statistical significance is a term in 6 statistics that usually refers to when the data, 7 there's less than a five percent chance that the 8 data can be explained by random phenomena.</p> <p>9 Q Would you agree that the chances of 10 complications of any sort in 2004 from CVS were 11 statistically insignificant?</p> <p>12 A No, it's ridiculous.</p> <p>13 Q They were one to two percent?</p> <p>14 A Yes, but it has nothing to do with 15 statistical significance. Statistical significance 16 would be they are statistically significant.</p> <p>17 Q Because they are explainable?</p> <p>18 A No, because they are observed. You 19 follow a certain number of pregnancies that you have 20 not been exposed to CVS and you follow a certain 21 number of pregnancies that have been exposed to CVS, 22 and you determine how many people miscarried who 23 didn't have CVS, and how many people miscarried that 24 did have CVS, and you set a 95 percent cap and come 25 up with a statistical result that says there is an</p>	<p style="text-align: right;">Page 179</p> <p>1 A Actually I have not.</p> <p>2 Q Do you know whether the failure rate 3 of condoms is higher than the failure rate of PGD 4 statistically?</p> <p>5 A I have no idea what the failure rate 6 of condoms is, I m sorry.</p> <p>7 Off the record.</p> <p>8 (Discussion off the record.)</p> <p>9 Q We have talked about a handful of 10 various potential causes of misdiagnosis.</p> <p>11 Are there any other possible causes of 12 a bad result that have any significance?</p> <p>13 A Well, I don't remember what we 14 discussed, so I'm sorry.</p> <p>15 Q Okay, well, we talked about allele 16 dropout pregnancy with a nonimplanted embryo.</p> <p>17 Can you rule out pregnancy with a 18 nonimplanted embryo in this case?</p> <p>19 A No, no.</p> <p>20 Q Mosaicism, DNA contamination, ADL as 21 discussed, pregnancy with a nonimplanted embryo, I 22 think those are the possible causes we talked about 23 of misdiagnosis?</p> <p>24 A That's sounds complete.</p> <p>25 Q Now, you read the transcript of Dr.</p>

EXHIBIT 32

Chaya Grossbaum.txt

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-1359

CHAYA GROSSBAUM and MENACHEM
GROSSBAUM, her spouse, individually
and as guardians ad litem of the
infant, ROSIE GROSSBAUM,

Plaintiffs,

vs.

DEPOSITION OF:

CHAYA GROSSBAUM
(VOL. 2)

GENESIS GENETICS INSTITUTE,
L.L.C., of the State of Michigan,
MARK R. HUGHES, M.D., NEW YORK
UNIVERSITY SCHOOL OF MEDICINE and
NEW YORK UNIVERSITY HOSPITALS
CENTER, both corporations in the
State of New York, ABC
CORPORATIONS 1-10 and JOHN DOE
1-10,

Defendants.

B E F O R E: NANCY J. GILMARTIN, a
Certified Shorthand Reporter and Notary Public of
the State of New Jersey at the office of
NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON,
ESQS., 20 Commerce Boulevard, Succasunna, New
Jersey, on Thursday, March 12, 2009, commencing
at 10:55 a.m., Pursuant to Notice.

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NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN
& KRON, ESQS.

Chaya Grossbaum.txt
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For the Plaintiffs

STEPHEN N. LEUCHTMAN, P.C.
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For the Defendants Genesis
Genetics Institute, L.L.C. and
Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN &
GOGGIN, ESQS.
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For the Defendants New York
University School of Medicine
and New York University
Hospitals Center

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I N D E X

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS
CHAYA GROSSBAUM				
By Mr. Eichhorn	209		334,342	
By Mr. Leuchtman		314		
By Mr. Stein		341		

C. Grossbaum - Direct

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1 care. They wait until like a couple of months I
2 think, a few months until you start getting
3 regular prenatal care.

4 Q Let me ask you this: At what point
5 in your pregnancy did you start with Midwives of
6 Denville?

7 A I believe I was a couple of months
8 pregnant.

9 Q So can you tell me about how long
10 you continued to follow with NYU until they
11 determined it was a viable pregnancy?

12 A I believe it was six weeks.

13 Q Six weeks. Okay. I misunderstood
14 your earlier answer.

15 And during those six weeks, how were you
16 monitored, with ultrasound?

17 A Ultrasounds and blood work to check
18 hormone levels. I had to continue taking
19 progesterone injections.

20 Q Then from once you began with
21 Midwives of Denville, was your interaction with
22 NYU completed?

23 A Yes.

24 Q And your pregnancy, was it, from
25 your perspective as a patient, was it uneventful

C. Grossbaum - Direct

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1 or did you have any particular difficulties?

2 A It was uneventful.

3 Q What testing, if any, did you
4 undergo during your pregnancy after you were
5 completed with NYU?

6 A All the blood work that's required,
7 the diabetes testing, the urine testing that they
8 do. I think I did one or two ultrasounds or
9 whatever. Yeah, all the basic tests.

10 Q And you gave birth to Rosie at what
11 hospital?

12 A St. Clare's in Denville.

13 Q Was that a normal spontaneous
14 vaginal delivery?

15 A Yes.

16 Q Any complications with it?

17 A No.

18 Q How long were you in the hospital?

19 A I gave birth Friday and I went home
20 on Sunday.

21 Q And am I correct you didn't have
22 any physical problems as a result of it?

23 A No.

24 Q And how about Rosie, how long was
25 she at St. Clare's?

C. Grossbaum - Direct

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1 A Same time.

2 Q So Friday, discharged Sunday you
3 said?

4 A Yes.

5 Q When did you learn that Rosie had
6 cystic fibrosis?

7 A When she was about two weeks old.

8 Q And please tell me what happened
9 that you learned that at that time.

10 A The state does testing in the
11 hospital, and we got a letter stating that they
12 weren't happy; that we should go see our doctor
13 because there was — the results showed that she
14 possibly had, you know, one of these issues. So
15 we — at the same time the doctor got the letter
16 and he also contacted us and we contacted him.

17 Q When you say "one of these issues,"
18 was it a form letter that gave a whole lot of
19 different —

20 A Yeah.

21 Q And CF was one of them?

22 A Yes.

23 Q Was there a check next to CF or did
24 it just give a list and it said your child may
25 have one of these?

C. Grossbaum - Direct

222

1 A I don't remember.

2 Q Do you have that letter still?

3 A I don't think so.

4 Q You said the state does testing.
5 Was the letter from the state or was the letter
6 from the hospital?

7 A I don't remember.

8 Q And it said that your child may
9 have one of these things or did have one?

10 A I don't remember the exact wording.

11 Q But, in any event, it recommended
12 that you see your doctor?

13 A Yeah. And I believe they also sent
14 the letter to the pediatrician.

15 Q And who was the pediatrician?

16 A Dr. Richard Dicker.

17 Q So did you contact Dr. Dicker or
18 did his office contact you about this issue?

19 A I contacted him, and at the same
20 time I believe he was also trying to contact us.

21 Q So, in any event, you contacted
22 each other somehow and I guess you brought Rosie
23 in to see him?

24 A We brought Rosie — he sent us I
25 believe directly to Dr. Atlas.

C. Grossbaum - Direct

223

- 1 Q So you didn't actually bring Rosle
2 to see Dr. Dicker as a result of this letter?
3 A No, because he got the letter -- I
4 think either he got -- he told us -- I don't
5 remember. I don't remember exactly what
6 information he got, but he sent us directly to
7 Dr. Atlas.
8 Q And what is Dr. Atlas' specialty?
9 A He's a pediatric pulmonologist.
10 Q Now, had Rosle seen Dr. Dicker in
11 his office at all since birth prior to you
12 getting this letter?
13 A I don't remember if he saw her in
14 his office. He was the pediatrician that saw her
15 in the hospital before you could be let -- let go
16 from the hospital. He was her pediatrician. He
17 saw her, and I don't remember -- I don't remember
18 if we went to his office like for just a regular
19 checkup when she was a week or so old. I just
20 don't remember. It's vaguely in my mind that it
21 was a possibility, but I don't remember.
22 Q And is Dr. Dicker still Rosie's
23 pediatrician?
24 A Yes.
25 Q So the first meeting with

C. Grossbaum - Direct

225

- 1 know, I'm not so clear on what all the details
2 is, but basically they attach some kind of thing
3 to her arm, if I recall correctly, and they wait
4 a certain amount of time and they check whatever
5 it is they see on the arm. I don't know exactly
6 how it works, but.
7 Q You called it a sweat test?
8 A I believe that's what he called it,
9 a sweat test.
10 Q Sweat as in sweating if you're hot?
11 A Yes. I think they check the salt
12 level -- again, I don't know the medical
13 information.
14 Q And just so you're clear, I'm not
15 asking you the medical, scientific explanation.
16 I'm asking you as the mother, from your point of
17 view, what you remember being done.
18 A So he had to -- they wanted to
19 confirm that they did their own blood work, their
20 own testing to see if she had CF. They weren't I
21 think so happy with the results. They didn't
22 think it was such a clear result because it
23 wasn't -- she was little and it wasn't on tight.
24 I don't know exactly the reason. So they did it
25 again. But it confirmed it and then he spoke to

C. Grossbaum - Direct

224

- 1 Dr. Atlas -- first of all, where is his office?
2 A At the Goryeb Children's Hospital
3 in Morristown Memorial Hospital.
4 Q And at about what age was Rosle
5 when you first brought her to see him or if you
6 remember the date you brought her to see him you
7 could tell me that?
8 A I don't remember the date. It
9 was -- she was about two weeks old.
10 Q Do you remember that visit as you
11 sit here?
12 A Yes.
13 Q Was your husband, Mendel, with
14 you?
15 A No.
16 Q You and Rosle?
17 A And my mother.
18 Q Your mother. Okay. Tell us,
19 please, what you remember occurring at that
20 visit.
21 A He did the I guess there's a sweat
22 test that they test to see if the child has
23 cystic fibrosis.
24 Q Tell me what that is, please.
25 A It's -- I don't -- medical, you

C. Grossbaum - Direct

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- 1 us a little bit about, you know, CF and what, you
2 know, what we would have to do a little bit and
3 kind of laid out like some information about we
4 would have to come see him more periodically when
5 she was younger, just information and talking
6 about it. And he introduced us to the people on
7 his team that he works with that we would see on
8 a regular basis.
9 Q Okay. Let me just get back to that
10 sweat test for a minute though. So he put
11 something on your daughter's arm. What was it,
12 as best from your perception?
13 A It was some kind of like I think it
14 was like a dye or something, a band that was
15 holding something in on it.
16 Q How long was it on?
17 A I believe it was for several hours.
18 Q And during those several hours, did
19 Rosle stay at the doctor's office?
20 A Yeah. We waited in the hospital.
21 Q And did the doctor have Rosle do --
22 I mean, she was obviously very young?
23 A Two weeks old.
24 Q He didn't have her do anything or
25 didn't put her on any kind of a machine. He just

C. Grossbaum - Direct

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1 put this on her arm, waited a few hours and then
2 checked it. Is that essentially what you recall?

3 A Yeah, but they did other -- I don't
4 remember exactly all the tests.

5 Q And I guess he knew the results
6 that day?

7 A I don't remember. I believe it was
8 that day.

9 Q Well, he put this on her arm, you
10 waited in the hospital for a number of hours, he
11 then saw her again and my question is do you
12 remember whether he knew the result that day and
13 gave you this explanation you described before
14 that day or some other day?

15 A I can't answer. I believe it was
16 that day, but I'm not a hundred percent sure. I
17 know we came back several times in that time and
18 I don't -- I'm not a hundred percent sure exactly
19 how it all played out.

20 Q That's fine. As I told you the
21 other day a few months ago when we did this, if
22 you don't remember something it's fine to tell me
23 that.

24 So, in any event, whether it was that day
25 or another day, there was a day that he told you

C. Grossbaum - Direct

229

1 A I was there for several hours. I
2 can't tell you that the conversation went for
3 this long. I was in the hospital for probably
4 the better part of the day.

5 Q Now, when you say you were there
6 the better part of the day, are you talking about
7 the day that you waited for several hours with
8 this thing on your daughter's arm or not?

9 A Well, because I'm not a hundred
10 percent clear on -- I don't remember exactly how
11 it played out, I believe it was that day and I
12 would think I was there for most of the day, but
13 we were there quite often in the first few weeks
14 so I don't remember exactly what happened on
15 every single visit.

16 Q My question is, putting aside how
17 long you were there, my question is, that initial
18 discussion, how long was that discussion, not how
19 long the whole time in the hospital was?

20 A I would say we met with him for an
21 hour or so, and then we met his whole team, the
22 dietician and the respiratory therapist and the
23 social worker. So we spoke with each of them for
24 a while. So I would say with him I spoke could
25 be an hour, between an hour, two hours. And then

C. Grossbaum - Direct

228

1 the results of the test?

2 A Correct.

3 Q And he told you that it confirmed
4 that Rosie had CF?

5 A Yes.

6 Q And you told us a little bit a
7 minute ago that he generally talked about CF and
8 gave you some information on what you would do,
9 that kind of thing, correct?

10 A Correct.

11 Q Do you remember who was in the
12 office that day, the day that he explained these
13 things to you?

14 A Who was in the office in general?
15 What do you mean?

16 Q I mean, you were there?

17 A I was there. My mother was there.

18 Q And Rosie was there?

19 A And Rosie was there.

20 Q So the day that he explained all
21 this to you it was you three that were there?

22 A I believe so, yes.

23 Q And do you recall about how long
24 the discussion was on that day when he told you
25 the results and gave you this information?

C. Grossbaum - Direct

230

1 the respiratory therapist was probably an hour.
2 Dietician, you know, I can't give you exact
3 times. I don't remember.

4 Q And I'm not asking for exact times.
5 What I'm asking for is an approximation, if you
6 can give me one without guessing. And if it's a
7 guess, tell me and I won't ask it again.

8 A An approximation would be probably
9 a couple hours with Dr. Atlas, and then I don't
10 remember with the other people, but it was enough
11 time for them to explain the different treatment
12 that I was going to start with and how, you know,
13 all those different things would work and enough
14 time that they were able to answer any questions
15 that I had.

16 Q Do you remember whether you had any
17 questions that day?

18 A Yes. I remember having a lot of
19 questions.

20 Q And other than Dr. Atlas, you said
21 you met I believe you said with a dietician?

22 A Yes.

23 Q And what other type of specialized
24 person did you meet with that first day?

25 A The respiratory therapist.

C. Grossbaum - Direct

231

- 1 Q Okay. Is that it or was there
2 anyone else?
3 A Social worker. I think that was
4 it. Kind of like one big --
5 Q I understand. Could you tell me,
6 as best you recall, when Dr. Atlas told you of
7 the result and gave you an explanation of what CF
8 is, what was your understanding of what he was
9 saying? In other words, I'm asking you, as best
10 you can, to tell me what he told you about what
11 CF is.
12 A He told us that it's a genetic
13 condition that affects the lungs and digestion,
14 and he gave us, you know, information about what
15 CF was, how they -- you want to know what he --
16 like the specific explanation he told me or
17 how -- can you clarify the question?
18 Q Yes. In other words, I understand
19 he's a doctor; you're not.
20 A Right.
21 Q He was giving a medical explanation
22 of a medical condition, but you're not a doctor
23 hearing it.
24 A Right.
25 Q So, from your perspective as a lay

C. Grossbaum - Direct

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- 1 person but as the mother, what is your
2 recollection of what he told you about what CF
3 is?
4 A Okay. It's a genetic condition
5 that there's no cure for; that it impacts the
6 lungs and digestion and how a person secretes
7 sweat and how they -- the mucus kind of passes
8 through their body, how they deal with mucus in
9 their body and bacteria.
10 Q What did he say about that, about
11 mucus in their body and bacteria?
12 A So like this is also not such a
13 clear memory of it, but basically when you and I
14 have mucus, we're able to -- it's able to pass
15 through the -- like the follicles in our body
16 easily. When someone has CF, it's much thicker
17 and it's much harder for it to move, so they're
18 at much greater risk of bacteria and bacterial
19 infections and can cause a lot of problems. They
20 have problems digesting food properly. I mean --
21 Q I'm just -- I'm not quiet just
22 because I'm --
23 A It's not a very good medical
24 explanation, but I don't have all the medical
25 knowledge.

C. Grossbaum - Direct

233

- 1 Q I understand. I'm not being quiet
2 because I'm expecting you to say more. I'm just
3 giving you the time to finish your answer. If
4 you're finished, that's fine. Okay. That's what
5 you recall him telling you generally about CF?
6 A General, yeah, basic thing of what
7 CF disease actually is.
8 Q And you mentioned that you had lots
9 of questions. Did you ask any questions of him
10 specifically? I know I'm going to get to your
11 discussion with the other people, but while we're
12 talking about him, let's deal with him. Do you
13 remember any questions you had for him?
14 A I don't remember like -- I remember
15 having a lot of questions wondering what my life
16 was going to be like, what her life was going to
17 be like, you know, obviously how would it affect
18 her, you know, how long she would live, what my
19 daily life -- what I would have to do to take
20 care of her. It was a lot of unknowns. You
21 know, it was just trying to get an idea of what
22 the heck was going on.
23 Q And do you remember the answer to
24 the questions of what will my life be like and
25 what will her life be like?

C. Grossbaum - Direct

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- 1 A He was very reassuring. He was --
2 he said, you know, we'll teach you everything you
3 need to know. It's going to take time to process
4 everything. You're not going to figure it all
5 out in a day. You know, we'll make sure that
6 whatever questions you need or if you need to be
7 explained something over and over, he just made
8 sure that I, you know, they would make sure we
9 would know what to do.
10 Q And in response to your question of
11 life expectancy or whether it would affect your
12 life expectancy, do you remember what the answer
13 was?
14 A I believe what he said is that
15 statistics say that the life expectancy of
16 someone with CF is about 30 years old.
17 Q Do you remember any other questions
18 that you asked him?
19 A I asked a lot of questions. I
20 don't remember. They said -- it was a lot of,
21 you know, what this is all about, what, you know,
22 there were a lot of questions.
23 Q Now, when you received the letter
24 that you mentioned from either the state or the
25 hospital, did that letter come as a surprise to

C. Grossbaum - Direct 235

1 you when you read that your child may have one of
 2 those listed conditions?
 3 A Yes. It was a surprise to get the
 4 letter.
 5 Q And can you tell me, since you
 6 don't believe you have the letter anymore, about
 7 how many different conditions were listed on that
 8 letter as something that your child may have?
 9 A No. I don't remember. Maybe -- I
 10 can't even guess.
 11 Q Well, if you can answer without
 12 guessing, was it more than five conditions?
 13 A I don't remember. I believe it
 14 was, but I don't remember a hundred percent,
 15 really can't.
 16 Q As you sit here now, do you
 17 remember any of the conditions that were listed
 18 other than cystic fibrosis in that letter?
 19 A I believe there was Tay-Sachs.
 20 There were some other ones that I really had
 21 never heard of before. I think there was like
 22 sickle-cell anemia or something, but I don't
 23 remember. There were some that I really had
 24 never even heard of and I didn't know what they
 25 were.

C. Grossbaum - Direct 236

1 Q Were you the person that opened
 2 that letter?
 3 A Yes.
 4 Q So you got it from the mail and you
 5 opened it?
 6 A It was already brought into the
 7 house, but I opened it.
 8 Q So you were the first one to read
 9 it?
 10 A I believe so.
 11 Q Was your husband there with you
 12 when you read it or did he learn about it later?
 13 A No. I think he was there. I don't
 14 remember. I was at a wedding and I had come
 15 home, and he wasn't with me at the wedding, but I
 16 don't remember. I think -- he was there at some
 17 point that night, but I don't remember if he was
 18 there as I opened the envelope. I might have
 19 read it and then went to find him, but I don't
 20 remember the exact -- if he was standing right
 21 there as I opened the letter.
 22 Q I don't really mean to ask whether
 23 he was there when you opened it. What I mean to
 24 ask is was he with you when you read the letter
 25 for the first time?

C. Grossbaum - Direct 237

1 A I believe so.
 2 Q You think he was?
 3 A Yes.
 4 Q Now, when you read the letter and
 5 you saw these different medical conditions, one
 6 of them being CF, did you look at the list and
 7 come to a conclusion in your mind as to which one
 8 of those conditions that they were probably
 9 referring to?
 10 A I didn't come to any conclusion,
 11 but I was very scared. I knew there was -- the
 12 letter was saying there was something wrong, but
 13 it didn't really give a lot of information, just
 14 said call your doctor. So kind of was like
 15 panicked, but it was in the middle -- it was
 16 really late at night. So I knew I had to wait
 17 until the morning to even call the doctor and
 18 called the doctor first thing in the morning.
 19 Q Do you remember what day of the
 20 week it was that you read that letter?
 21 A No. It was a weekday though. It
 22 wasn't a weekend.
 23 Q So you were at a wedding on a
 24 weekday?
 25 A Yeah. That's pretty common in

C. Grossbaum - Direct 238

1 orthodox circles.
 2 Q Okay. See, I'm learning more.
 3 MR. STEIN: No Saturday weddings.
 4 A Yeah, there's never a Saturday
 5 wedding.
 6 Q You could have a Sunday wedding
 7 though?
 8 A Sunday wedding you could have.
 9 Q Whatever. That was my ignorance.
 10 So when you looked at that letter and you
 11 looked at that list and you saw CF, did you think
 12 anything through in your mind about, oh, my gosh,
 13 if it's one of these things it's probably CF or
 14 did you not really have that thought process at
 15 that time?
 16 A I mean, I knew it was most likely
 17 not sickle-cell anemia. I knew I wasn't a
 18 carrier for Tay-Sachs. Some of the ones I had no
 19 idea what they were. I thought that if they sent
 20 me this letter, there, A, may have been a
 21 mistake, that maybe they, you know, I don't know,
 22 made a mistake or that it could be CF or
 23 something else that I had no idea what it was. I
 24 was panicked. I knew according to the letter
 25 something was wrong, but some of the things I

C. Grossbaum - Direct

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- 1 didn't even know what they were.
- 2 Q Did you and your husband have any
- 3 discussion about that letter when you two read
- 4 it?
- 5 A There was a lot of panic on my part
- 6 and melting down. There wasn't much I don't
- 7 think logical discussion. I was very freaked
- 8 out, crying, upset, worried. I didn't sleep all
- 9 night wondering what was going on.
- 10 Q So --
- 11 A It was a lot of talking like that,
- 12 like what's the problem, what's going on, what do
- 13 you think is going on? But we didn't have any
- 14 answer. It was just a lot of like, oh, my God,
- 15 what's happening?
- 16 Q So did your husband say anything
- 17 about the issues raised by that letter other than
- 18 him maybe trying to calm you down?
- 19 A No. At that point it was just
- 20 relax, calm down. We don't have any information.
- 21 We'll speak to the doctor. Don't panic yourself.
- 22 Don't get yourself upset. We'll speak to the
- 23 doctor and find out what's going on.
- 24 Q So the next morning you called
- 25 Dr. Dicker?

C. Grossbaum - Direct

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- 1 A Yes.
- 2 Q And then you went to see Dr. Atlas?
- 3 A Yes. It was all within a few days.
- 4 Q In those few days between reading
- 5 the letter and between seeing Dr. Atlas, did you
- 6 speak with any physicians about this issue?
- 7 A Dr. Dicker, and I believe at that
- 8 time Dr. Dicker told me that they believed that
- 9 the issue was cystic fibrosis.
- 10 Q And when he told you that, did you
- 11 have any questions for him at that time?
- 12 A Yeah. I asked him also about
- 13 what -- little bit about what CF was, but he had
- 14 a very basic knowledge of it and he said, you
- 15 know, I want you to go to this specialist. He's
- 16 a really good doctor and he'll really be able to
- 17 guide you and help you.
- 18 Q When you spoke to Dr. Dicker on the
- 19 phone, was your husband also on the phone or --
- 20 A No.
- 21 Q -- was it just you?
- 22 A Just me.
- 23 Q Was that a short conversation,
- 24 short meaning five minutes or less?
- 25 A No. It was more than five minutes.

C. Grossbaum - Direct

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- 1 It was probably 20, 30 minutes.
- 2 Q Oh, okay. And in those 20 or 30
- 3 minutes he was telling you what?
- 4 A He said a little about what cystic
- 5 fibrosis was, telling me about Dr. Atlas, basic
- 6 stuff like that, you know, 30, maybe 10, 20
- 7 minutes.
- 8 Q After that discussion, did you
- 9 speak to any other physicians before the office
- 10 visit with Dr. Atlas?
- 11 A No.
- 12 Q Did you seek out anyone to talk to
- 13 about this issue before you saw Dr. Atlas, other
- 14 than Dr. Dicker? So I'm not limiting it to a
- 15 physician but anyone. Did you go seek out anyone
- 16 to speak to specifically about this during that
- 17 time frame?
- 18 A I mean, I spoke to lots of family
- 19 and friends and people close to me, but it was a
- 20 very short amount of time. It was like a day or
- 21 two from when I got the thing to when we saw Dr.
- 22 Atlas.
- 23 Q And in those discussions, did you
- 24 learn anything about CF that Dr. Dicker hadn't
- 25 told you?

C. Grossbaum - Direct

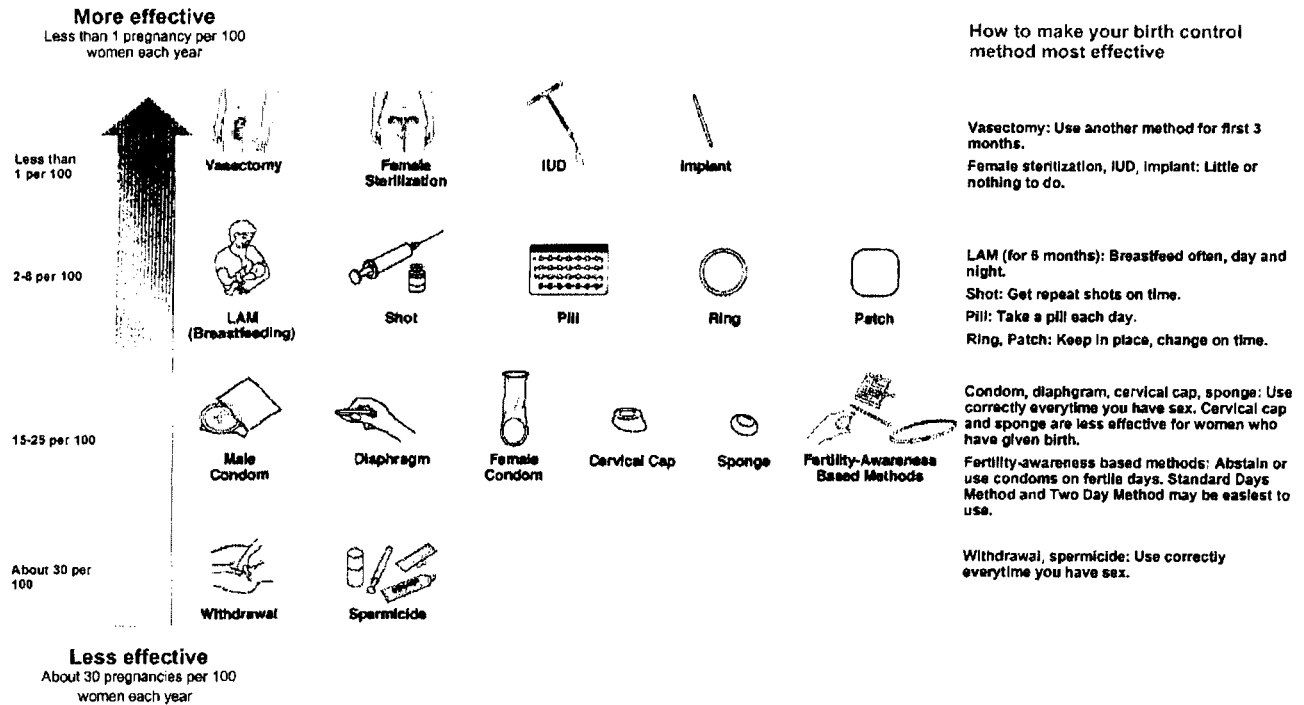
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- 1 A Not at that point, no. More like
- 2 supportive phone calls.
- 3 Q Did any of the people that you
- 4 spoke with have any personal knowledge of CF?
- 5 A No.
- 6 Q And when you were in Dr. Atlas'
- 7 office and as he was giving you the explanation
- 8 of what CF is and the things you told us a few
- 9 minutes ago, were you there alone or was your
- 10 husband there or someone else there?
- 11 A At the first visit?
- 12 Q Yes.
- 13 A My mother.
- 14 Q Okay. And what was your reaction
- 15 when you were having this first meeting with
- 16 Dr. Atlas?
- 17 A I was crying. I was scared. I was
- 18 very upset, uncertain of what was going to happen
- 19 to my life, worried about my child, scared for
- 20 her, sad, very upset, shocked. I mean, every
- 21 emotion you could possibly go through I felt.
- 22 Q And what was the reason for the
- 23 shock? Why were you shocked?
- 24 A Well, because I went to such
- 25 lengths to prevent that from happening, I never

EXHIBIT 33

Comparing effectiveness of birth control methods

Click on the picture of each birth control method to learn about it



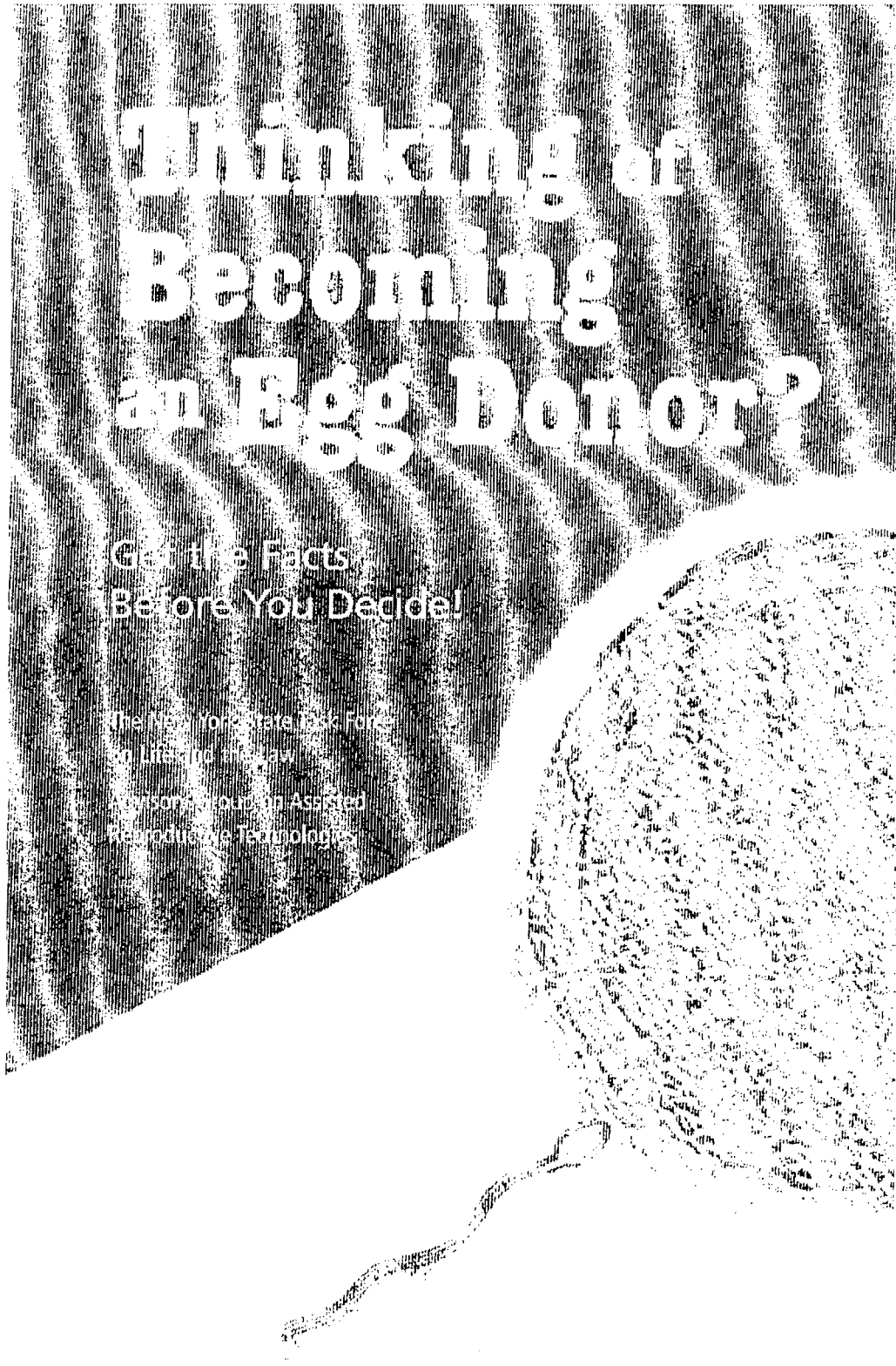
Source: Adapted from WHO, 2007

EXHIBIT 34

Thinking of Becoming an Egg Donor?

Get the Facts
Before You Decide!

The New York State Task Force
on Life and the Law
Task Force Report on Assisted
Reproductive Technologies



The New York State Task Force on Life and the Law was created in 1985 to develop public policy on issues arising from medical advances. The Task Force includes leaders in the fields of law, medicine, nursing, philosophy, consumer rights, religion and ethics.

In 1998, after extensive research and interviews with people involved in fertility treatment, the Task Force found that egg donors frequently are not adequately informed about the process. The Task Force received a grant from the Ford Foundation to create a model process and form for obtaining informed consent, and this guidebook for egg donors.

This guidebook was prepared by the Task Force's Advisory Group on Assisted Reproductive Technologies. The Group included infertility specialists, consumers, ethicists, Task Force members, and representatives of the American College of Obstetricians and Gynecologists and the Society for Assisted Reproductive Technology. In addition, egg donors shared their experiences with the Group and Task Force staff.

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INTRODUCTION

Many couples who want to have children find it difficult or impossible to conceive. Using special techniques, some couples can conceive using their own eggs and sperm. Others must use sperm donated from another man. More recently, egg donation has allowed some women, whose ovaries do not produce enough healthy eggs, to become pregnant using donated eggs.

You may be reading this guidebook because you answered an ad for egg donors or were asked by a friend or relative to consider becoming a donor. If so, you need to learn all you can about the process and think seriously about what it involves before you start. Becoming a donor is a very important decision.

This guidebook provides prospective egg donors with unbiased information. It suggests issues for you to consider and questions to ask before deciding whether or not to become a donor.

WHO CAN BECOME AN EGG DONOR?

Not all women can donate eggs. Programs vary in the qualities they prefer, but some criteria are fairly standard. Certain rules are set for legal reasons. Other policies are designed to increase the chance that a pregnancy will result and that the process will be safe for both donor and recipient.

Commonly, egg donors must be a certain age, usually 21, and be no more than 35. The lower limit ensures that a woman can legally enter into a contract. The upper limit reflects the fact that older women respond less well to fertility drugs. There is also a chance that an older woman's eggs will be abnormal, making pregnancy less likely or increasing the risk of a birth defect.

Some programs prefer to use donors who have already given birth or successfully donated eggs. It is believed that they are more likely to be fertile and it is easier to anticipate their feelings about having genetic offspring born to someone else.

WHAT DOES EGG DONATION INVOLVE?

If you apply to become an egg donor you may have several medical visits before you are accepted. These visits will include a physical and gynecological exam, a medical and family history, blood and urine tests, and a psychological evaluation. You will also discuss your rights and responsibilities with a program representative. A donation will not occur unless you are accepted, matched with a woman who will receive your eggs, and give your consent.

Using donated eggs to establish a pregnancy involves *in vitro fertilization* (IVF). First, you will take a series of fertility drugs (some of which must be injected) to stimulate your ovaries to produce many eggs at one time. While using the drugs, you will have frequent medical tests. Removing the eggs from your ovaries involves a minor surgical procedure. After you recover from egg retrieval, your part of the treatment cycle is finished.

Your eggs will then be mixed with sperm from the intended father in the clinic's laboratory. If embryos result, they will be grown in a lab dish before one or more are transferred into the uterus of the recipient. If she becomes pregnant and delivers a child, she will be the birth mother and legal mother of that child even though the child will be genetically related to you.

WHAT SHOULD I KNOW ABOUT ADS FOR EGG DONORS?

When you answer an ad for egg donors, it is important to find out who placed it. Many infertility programs advertise for egg donors to help treat their patients. These programs provide all the screening, matching, and medical procedures required by the donation.

In some cases, ads are placed by egg brokers. These individuals or organizations recruit egg donors but do not provide medical services. If you contact a broker, be sure to find out who is responsible for each part of the egg donor process. Will you be screened by the broker? Will an infertility program want to repeat those tests? Who will pay your medical bills? What will happen if you develop complications? What will happen to information you provide?

Occasionally, advertisements – supposedly on behalf of a specific couple – will offer a large amount of money to the right egg donor. These ads seek donors with special qualities, such as above-average height, athletic or musical ability, or an Ivy League education. Be aware that, in some cases, there is actually no couple willing to pay the enticing fees. Instead, a broker is trying to attract a large number of applicants. Details about these applicants will be used in the broker's advertising or on its Web site to attract recipients. Some brokers will use the information you give in these ways unless you specifically refuse permission.

You may receive a phone call offering a much lower fee to serve as a donor to another couple. Even if you are never called, information from your application may become available on the Internet.

Remember, the purpose of an ad is to entice you to become an egg donor. Do not rely on an advertisement for details about the process. You will need to read any educational materials and consent forms carefully. Ask questions until you understand the process well enough to make a decision.

HOW ARE EGG DONORS SELECTED?

If you answer an advertisement, you may be interviewed over the telephone, or be sent an application to fill out. Based on your responses, the program may decide that you are unlikely to be chosen, and you may not hear from them again.

If the program decides that you are likely to be chosen, you may be invited to proceed with the selection process. Before you are accepted as an egg donor, however, you will be required to undergo medical and psychological screening.

Before you are screened, program staff should thoroughly describe the procedures and risks involved in donation. That way, if you decide not to proceed, you can avoid the screening process. In any case, do not give your written agreement to become an egg donor before the screening process is complete. After you are screened, you should have access to the results of your medical tests – whether or not you become a donor.

General medical screening: You will have a physical examination, including a pelvic exam. Blood will be drawn to check your hormone levels.

Ultrasound (which uses sound waves, not X rays) will be used to examine your uterus, ovaries and other pelvic organs. These tests might reveal an existing health problem. If anything is found, ask about your options for treatment (either from the program or another health professional).

You will complete a detailed medical and psychological history about yourself and close blood relatives. It will include questions about your use of cigarettes, alcohol, and both prescription and illegal drugs. Many programs conduct unannounced drug tests during the screening and donation process.

Infectious disease screening: When blood or tissue is transferred from one person to another, it can carry viruses or bacteria. To minimize the risk that a donor egg could cause illness in the recipient, donors are tested for a variety of infections.

During your pelvic exam, a small scrape from your cervix will be taken to test for gonorrhea and chlamydia. Blood will be drawn to test for syphilis, hepatitis B and C, and HTLV-1 (a very uncommon virus that is associated with some cancers).

You will have a blood test to see if you have been exposed to HIV. New York State Law requires that you consent to this test in writing, after you read about the pros and cons of the test and understand who can receive the results.

Although there has never been a report of this happening, a program should not accept any egg donor who is at increased risk for exposure to HIV or other infections. According to State regulations, you may not donate eggs if you have injected drugs or been engaged in prostitution within the last five years. You are not eligible to donate eggs if, within the last year, you have been diagnosed with syphilis or if you have received acupuncture, a tattoo or body piercing without being certain that sterile procedures were used. If you have had more than one sexual partner in the last six months, you are not eligible to donate eggs. The program may also require your sexual partner(s), if any, to be tested for HIV.

Before you are screened for infectious diseases, make sure you understand the tests, and whether and how you will be given the results. If you have an infection, seek medical treatment to protect your own health and fertility.

Screening for inherited disease: Most programs try to learn all they can about a donor's genetic make-up in order to minimize the chance that a baby will have a birth defect or serious inherited disease. You will be required to provide your complete medical history. You will be asked medical questions about your biological parents, grandparents, brothers and sisters. The program may tell you what information to collect, or they may have you work with a genetic counselor to identify:

- Any birth defects that required surgery or resulted in medical problems (such as a cleft lip, spina bifida or a heart defect).
- Certain genetic disorders (such as Huntington's disease, hemophilia, Tay Sachs disease or sickle cell anemia).
- Inherited diseases that are of special interest to a recipient because of her own family history.
- Any major medical problems, surgeries, mental retardation, or psychiatric problems.

For any close blood relatives who have died, you will need to know how old they were and the cause of death. Some common diseases (such as cancer or heart disease) that strike when people are middle-aged or younger are influenced, at least in part, by genetics.

If you do not have access to the necessary information, either because you are adopted or there is no informed person to ask, you should not become an egg donor.

Some programs do a large number of genetic tests on all donors. Others select specific tests for each donor. Some tests are required by state law. A program may check for disease genes that are common in the ethnic group of either the donor or recipient. You might be tested to address a genetic concern in the family of the recipient, or to answer questions raised by your family history.

Genetic tests usually involve a simple blood test. However, genetic testing may give you information for which you are not prepared or need help to understand. For example, what if you carry a gene that puts you at high risk for breast cancer, or a gene that might create a risk of serious disease in your children? Or, what if you are rejected for medical or life insurance because of your genetic test results? Before undergoing genetic testing, find out:

- Will you receive the results?
- Is a genetic counselor available? If not, will the program refer you to one?
- Will the program give anyone else the results, such as your doctor or insurance company?
- How might the results influence your ability to get insurance coverage in the future?

Psychological screening: Donating eggs requires you to confront complex ethical, emotional and social issues. The screening process should help you evaluate your desire to donate and to think through these issues.

You should have a chance to ask questions and express any concerns. In most programs, you will meet with a mental health professional to discuss your life circumstances, your support system, your feelings about the donation, and related issues. In addition, many programs ask donors to take psychological tests.

Another goal of psychological screening is to make sure that you will fulfill the complex requirements of egg donation. Failure to follow instructions can endanger your health and jeopardize the procedure. The program also wants to minimize the chance that you will have regrets or psychological problems, or find the procedures traumatic.

Before you decide to participate, you must try to foresee how you will feel about donating your eggs and the possibility that children will be created who are genetically related to you. You may want to discuss these issues with your spouse, a relative or a trusted friend.

The program should offer you psychological counseling and support throughout the decision making and donation process. Talking with an independent counselor can be helpful, too. If you need help finding one, the program should be able to refer you to an independent counselor who is familiar with infertility treatment issues. The goal of counseling is not to convince you, or help you "adjust" to the program's demands, but rather to better allow you to decide, of your own free will, whether you wish to donate your eggs.

No matter how motivated, most donors do not find the process easy. Take advantage of counseling services offered through the program, and think about who might serve as a good support person.

Organized religions hold various opinions about whether it is appropriate to use donor eggs and sperm in the creation of children. If these views are important to you, you may want to consult a religious advisor before you decide.

The American Society for Reproductive Medicine suggests that a woman should *not* donate eggs if she:

- Has a serious psychological disorder.
- Abuses drugs or alcohol or has several relatives who do.
- Currently uses psychoactive medications.
- Has significant stress in her life.
- Is in an unstable marriage or relationship.
- Has been physically or sexually abused and not received professional treatment.
- Is not mentally capable of understanding or participating in the process.

If any of your close, blood relatives have serious psychiatric disorders, the program needs to know, because some psychiatric disorders may be inherited.

WHAT IF I AM NOT ACCEPTED?

It's natural to feel rejected if you are not chosen. Sometimes the decision is made to protect you from medical harm. Or, it might become apparent that you may find the process too time-consuming or emotionally difficult. In some cases, it simply means that the right match has not been found.

To prevent prospective donors from dwelling on the reason they were not accepted, some programs will not provide this information. If that is the policy where you are applying, make certain you are comfortable with that before going through the screening.

WHO WILL USE MY EGGS?

Egg donation is a treatment option for women who do not produce enough normal eggs but are otherwise able to be pregnant. Some of these women have malfunctioning ovaries or entered menopause at an early age. Others are at an age when they produce eggs less readily, even with fertility drugs. Still others tried standard IVF but produced poor quality eggs or embryos.

Less commonly, women decide to use donor eggs because they are aware of an increased risk for inherited disease in their biological offspring. For example, the woman herself may be healthy, but she and her partner may both carry a gene for the same disease. This creates a risk in the child if it inherits the altered gene from both parents. Using an egg donor who does not carry the gene eliminates this risk.

Who will use your eggs depends on the policies of the program. Most often, donor eggs are used by women in their late 30s or 40s who are attempting to become pregnant. Very few women under the age of 36 use donor eggs. Programs have various upper age limits for recipients. Some programs will allow women over age 50 to be recipients.

Most programs will treat unmarried women who are trying to become pregnant without a male partner and who require donor *sperm* as well as donor eggs. Some programs match an egg donor with more than one recipient.

If you have concerns about who might receive your eggs, discuss them with the program before agreeing to become a donor. Some programs allow donors to place restrictions on the use of their eggs. However, no program can guarantee how your eggs will be used.

WILL THE RECIPIENT KNOW WHO I AM?

Most programs keep the identity of donors confidential (often called "anonymous donation"). If you enter one of these programs, the recipient will have important information about you, but you will never meet or know each other's names. Other programs are more open. They may accept:

- Donors willing to be identified later: Some donors give permission to be contacted once the child reaches a given age.
- Donors willing to meet the recipients: In some programs, the donor and recipient meet to get to know each other and to ask questions.
- Donors who want ongoing relationships with recipients:
Some programs help donors maintain contact with the recipients, through an occasional photo or card, or a closer role as a special family friend.
- Donors who already have relationships with recipients: A recipient may contact a fertility program after she has already asked a friend or relative to donate.

No single type of arrangement is right for everyone. Each presents unique challenges during and after the donation.

HOW ARE DONORS MATCHED WITH RECIPIENTS?

In most infertility programs that use "anonymous" donors, program staff match a recipient with the donor who most closely resembles her, including ethnicity, height, body build, skin type, eye color, and hair color and texture. Once a possible match has been found, the recipient is given information about the donor and decides whether to proceed or wait for another donor.

In some programs, recipients are given information about several possible donors and select the match they would like to pursue. Donors may be asked to take intelligence tests or to provide other information (essays, childhood photos, school transcripts, lists of hobbies, etc.) that will be given to possible recipients. Other programs, however, do not provide this type of information because it implies, without good evidence, that these characteristics are largely determined by genetics.

WHAT IF SOMEONE ASKS ME TO DONATE?

Some women donate eggs to help a relative or friend who has been unable to have a child. These are often called "known donors."

If someone asks you to donate, it does not automatically mean you can. In New York State, a "known" donor must undergo the same screening as an "anonymous" donor. In addition, the program will make certain that you are not feeling pressured to take part because of your emotional or financial ties to the recipient. For example, you may not be allowed to donate eggs to your boss or to your mother. Because of the risk of inherited disease, you will not be allowed to donate eggs if you are a close blood relative of the intended father.

As a known donor, you must be ready for problems that might emerge later. How will your relationship with the recipient change? What will the child and other family members be told? Will you feel comfortable being an "aunt" or "family friend" to your genetic child?

Even when pregnancy does not occur, egg donation can still have a long-lasting impact on a donor's relationship with her relative or friend.

It is valuable (and often required) for a known donor and recipient, along with their spouses, to meet together with a counselor, as well as separately.

WHAT IS THE EGG DONATION PROCESS?

These are the standard steps in the process and the risks:

Stopping your normal cycle: You may be prescribed a medication for one or more weeks to temporarily halt your ovaries' normal functioning.

This makes it easier to control your response to fertility drugs. A doctor or nurse will give you an injection or instruct you about how to inject the medication daily at home.

The risks: The medications can cause hot flashes, vaginal dryness, fatigue, sleep problems, body aches, mood swings, breast tenderness, headache, and/or vision problems.

Stimulating egg production: In a normal menstrual cycle, one egg matures and, at ovulation, is released from an egg-containing sac (called a *follicle*) on the ovary. In egg donation, the goal is to obtain several mature eggs. You will be prescribed medication to stimulate your ovaries to mature more eggs than normal (called "controlled hyperstimulation"). The medications are similar to the hormones that your body produces, but at much higher doses. These medications must be injected (either under your skin or into a muscle). Treatment will start on a specific day of your cycle and continue for about ten days. You will be shown how to inject the medications. If you are unable to inject yourself reliably, you will need someone else to do it for you.

The risks: You may develop soreness, redness or mild bruising around the injection site. You may experience mood swings, tender breasts, enlarged ovaries and mild fluid retention. Occasionally, the medications cause more hyperstimulation than intended (known as "ovarian hyperstimulation syndrome," or OHSS). This will cause fluid retention and swelling of the ovaries. In mild OHSS, you may have abdominal pain, pressure and swelling. This should go away after your next period. In moderate OHSS, you may require careful monitoring, bed rest and pain medication. Severe OHSS is rare but can cause serious medical complications, including blood clots, kidney failure, fluid build-up in the lungs, and shock. In rare cases, hospitalization is necessary and the condition can be life-threatening. One or both of your ovaries may have to be removed. The risk of OHSS decreases after the eggs are retrieved.

If you show signs of OHSS before the eggs are ready to be retrieved, the doctor may decide that it is too risky for you to keep taking the hormones. You must stop using the medication and the cycle will be canceled.

If you decide, for some reason, not to undergo egg retrieval after having completed fertility drugs, you increase your risk of OHSS.

Very rarely, an enlarged ovary will twist on its stalk and cut off its blood supply. This painful condition requires immediate surgery and the ovary may have to be removed. Also, very rarely, a woman has an allergic reaction to fertility drugs.

You can become pregnant during the cycle, if you have unprotected intercourse. This could occur if some of the eggs are released before retrieval, or if the doctor is unable to retrieve all of the mature eggs. There is a chance that you could become pregnant with twins, triplets or quadruplets. You must abstain from intercourse or use effective barrier contraception. Ask the doctor about restrictions on intercourse during the donation cycle.

The long-term risks of fertility drugs are unknown. A few studies suggest that fertility drugs might increase a woman's risk for developing ovarian cancer later in life. Others do not show this link. At this time, no one knows for sure.

Monitoring your progress: During the donation cycle, you must have frequent blood tests and ultrasound examinations to track the developing eggs and to see how you are responding to the hormones. Based on these tests, you will be told how to adjust the dose of medication. The ultrasound exams involve inserting an ultrasound probe (about the size of a tampon applicator) into your vagina so the doctor can see the growing follicles on your ovaries.

When the time is right, you will receive a final injection of another drug to prepare the eggs for retrieval. This injection is given shortly before egg retrieval.

The risks: Blood drawing can cause mild discomfort and there is a chance you will develop a bruise in the area where the needle was inserted. Ultrasound examination may be slightly uncomfortable but has no known risks.

Removing the eggs: The eggs will be removed from your ovaries in a minor surgical procedure called *transvaginal ovarian aspiration*. An ultrasound probe will be inserted into your vagina. A thin needle attached to the probe will be inserted into each follicle. Using suction, the egg and liquid inside each follicle are removed. You may be given painkillers, sedatives or anesthesia during the retrieval, which lasts about 30 minutes. When all the eggs have been retrieved, you will recover for a few hours before going home. You must have someone drive you home. Afterwards, you will need to rest for the day. Often, it takes several days of restricted activity to recover.

The risks: After the needle is inserted into the ovary, there may be bleeding. Although rare, it is possible to damage or puncture the bowel, bladder or nearby blood vessels. In the unlikely possibility of severe internal bleeding or serious damage to the pelvic organs, major abdominal surgery may be needed.

To prevent infection, you may be given antibiotics. If infection occurs, it may affect your own future fertility. Ask the doctor about the risks of all medications used during retrieval.

Follow-up care: You should be given clear instructions about what to do if you need medical attention. In some programs, donors return for one or two check-ups. You may also be scheduled to meet with a counselor.

Many programs do not provide follow-up care, and it is normal for a donor to feel let down after her intense involvement in the process ends.

Many women are concerned that giving up some of their eggs may reduce their ability to later become pregnant. If there are no complications, being an egg donor should not affect your later fertility. However, if you develop serious complications, involving bleeding, infection, or loss of an ovary, it may jeopardize your ability to conceive.

WILL DONATING EGGS AFFECT MY EVERYDAY LIFE?

Egg donation is time-consuming. During the donation cycle, you will be given medications for about three weeks, and you will make several visits to the program for blood tests and ultrasounds.

You will be responsible for arranging your work or school schedule to fit the demands of egg donation. Some donors find it difficult to continue their normal activities. They have trouble keeping up at school or on the job, and in fulfilling their family responsibilities.

You will be required to refrain from drinking alcohol, smoking cigarettes and using illegal drugs. You will not be able to use any prescription or non-prescription drugs without permission. If you are in a sexual relationship, you must abstain from unprotected intercourse during specific weeks of the treatment cycle.

WHAT HAPPENS TO THE DONATED EGGS?

You must be aware that many things can happen to your eggs after they are removed from your ovaries:

- No embryos may be formed. This may be due to a sperm problem, the condition of the eggs, or a problem in the laboratory. Immature or unfertilized eggs can be discarded as medical waste or used in research.
- Pregnancy may not occur or may end in a *miscarriage*. More than half of egg donor cycles do not lead to successful pregnancies, even when embryos are formed and transferred.
- The recipient may become pregnant with more than one fetus. She and her doctor will decide how many embryos to transfer at one time. Pregnancies involving two or more fetuses are at higher risk of various complications, including miscarriage, premature birth and infant death. If the recipient becomes pregnant with a dangerously high number of fetuses, she may choose to undergo *multifetal pregnancy reduction*. In this procedure, a lethal chemical is injected into one or more fetuses to lower the number that continue to develop and decrease the risk that the entire pregnancy will be lost or end prematurely.

- More embryos may develop in the laboratory than can safely be transferred to the woman's uterus. The remaining embryos may be frozen and kept in storage for later use. You cannot be certain when a genetic child of yours may be born – it could be nine months or even years after your donation.
- The eggs may go to more than one recipient. One or more women may conceive, using your eggs, now or years from now. Or, no pregnancies may occur.
- The original recipient may never use the frozen embryos. The program may ask the recipient to: donate the embryos to another couple; donate the embryos to research; leave the embryos frozen indefinitely; or allow the embryos to be destroyed.

Once you donate your eggs, their fate is entirely up to the recipient.
You have no say about what happens.

WHAT IS INFORMED CONSENT?

A doctor must obtain your informed consent before treating you. But informed consent is more than a form to be signed. It is the process of helping you fully understand and agree to the medical procedures. Before you give your consent, the doctor who will provide your care should meet with you and answer your questions. If you wish, you should also be able to discuss any concerns or doubts with a nurse, social worker or counselor.

Before giving your consent for the procedures involved in egg donation, you should understand:

- What is involved in each procedure.
- If each procedure is:
 - 1) generally accepted as effective and safe by fertility specialists (although thorough research may or may not have been conducted); or
 - 2) new and innovative and not generally accepted among fertility specialists.

- How much experience the program has with each procedure, including the level of training of the professional staff.
- The risks of all medications and procedures, and what will be done if complications occur.

You can change your mind. You cannot be forced to undergo medical procedures against your will. Many programs acknowledge that a donor may withdraw her consent to participate at any time before retrieval of the eggs. Before consenting to donate eggs, make certain you understand and agree to the program's and/or the broker's policy on withdrawing consent.

ARE THERE OTHER LEGAL AND FINANCIAL CONSIDERATIONS?

Contracts: You may be asked to sign one or more contracts with the program and/or the recipient. These contracts may detail your responsibilities and those of the recipient and the program. Contracts are different from consent forms, because they may be legally binding.

Do not sign any contract before you have completed the informed consent process. Do not sign any contract that you do not fully understand. Some programs may require you to meet with a program lawyer to discuss the provisions of the contract. These lawyers represent the program's interests, not yours. You may wish to get independent legal advice before signing.

Confidentiality: A program or broker will gather a great deal of information about you from your application and throughout the screening process. In order to donate, you must agree to let a program disclose certain information to potential recipients of your eggs. If you are donating anonymously, the recipient should not be given your name or any information that can be used to identify you.

Before giving any information to an agency or a broker, ask about all the ways it may be used. Do not apply unless you are comfortable with the answers.

If you donate eggs and it results in the birth of a baby, State regulations require the program to keep certain information about you on file. Some of this information may be available to the child. According to current State regulations, no information will be released (unless you give permission) that would allow a child to identify you as the donor. However, it is possible that confidentiality laws and regulations may change in the future. In addition, a program cannot guarantee that someone will not discover confidential information by unauthorized means.

You should also be told under what circumstances, if any, a program might contact you in the future. Do they ever call previous donors to ask them to participate in research? Would you be contacted if the child has an inherited disease or needs a bone marrow transplant?

Parental rights and responsibilities: Once your eggs are retrieved, you have no control over what happens to them. You bear no responsibility for the outcome of the pregnancy. Any documents you sign should make it clear that the recipient is legally and financially responsible for any children that result, no matter what their condition. Ask to see the documents that she will sign, as well.

Although the clear intent is for the recipient to become the legal parent, this is a fairly new area of law and one that most state laws do not address specifically. A program cannot guarantee that this legal understanding will hold up in court (if a dispute arises) or that current laws will stay the same. However, it is extremely unlikely that you would be able to establish yourself as the legal mother of any child born as a result of your donation.

Payments: Most fertility programs offer payment to egg donors for their time, effort and discomfort. It is not payment for the eggs themselves and should not depend on the outcome.

If a cycle must be canceled before eggs are retrieved, some (but not all) programs provide partial compensation (often based on the number of days of treatment completed). After egg retrieval, you should receive the full, agreed-upon amount no matter the number or quality of the eggs.

Before signing an agreement, make sure you understand how you will be paid — directly by the recipient, or by the program? Will the program have the money in hand before the cycle starts? Is there any payment for donors who are screened but not selected? What is the payment (if any) if a cycle is canceled prior to retrieval?

According to the Internal Revenue Service (IRS), you must pay taxes on any money you receive for donating your eggs. The program must report how much they pay you, and you should receive a Form 1099 to use in preparing your tax return. Find out if the program will do the necessary IRS reporting and if it will withhold taxes from your payment.

Usually, there is no financial compensation when a woman donates eggs to a relative or friend. If you arrange to be paid outside of the program, the program will not be able to protect you if things do not go as planned.

Expenses: Think about what it will cost you to participate. This may include days off from work, transportation to the program, baby-sitting, or other expenses. Find out what records you need to keep, and if you will be reimbursed by the program or recipient.

Insurance: In most cases, your medical bills for procedures involved in the donation will be paid, in full, by the program or the recipient. Make sure that this is clearly stated, in writing, before you sign up.

In some programs, donors are required to have their own medical insurance. Ask under what conditions any treatment will be billed to your insurance. In most cases, no planned expenses will be billed to your insurance. However, if complications develop, your insurance may be billed.

Some programs will not accept a donor who does not have insurance. Others will arrange special, short-term insurance to cover you in the event of medical complications. If this is the case, you need to know:

- Who will pay the insurance premium?
- How long will the coverage last? What if you have long-lasting medical complications? What if a problem arises several months after you have completed your donation?

- How do you access care under the policy? Do you see your private doctor or must you first return to the program?

If no insurance is offered, you need a clear agreement, in writing, of how bills will be paid for complications. If there is a general statement, such as the program "covers all expenses," there are still likely to be restrictions and limitations. Is there a limit on the amount paid? If the recipient is supposed to pay, is it up to you or the program to collect the money? What about problems that appear later? What if you are unable to work or need special care?

Before starting a cycle, you may be asked to sign a statement that waives your right to sue the program for medical malpractice, pain and suffering, or any other expenses resulting from complications. You should consult with an attorney before you sign any such waiver. Even if you do sign, you can still sue to recover any medical expenses, pain and suffering, and other costs associated with injuries or complications caused by the negligence of the program. In the unlikely event that you are injured or have medical complications, and the program is unwilling to assist you, you should see an attorney.

CAN I DONATE MORE THAN ONCE?

There are no firm rules about how many times a woman can donate her eggs, but there are several reasons why a program may limit repeat donations. For one thing, there are still unanswered questions about the possible long-term impact on a woman's health and fertility. Because of this, programs are often reluctant to expose a healthy woman to the process more than a few times.

Programs are required, by the American Society for Reproductive Medicine and the State Health Department, to limit the number of children created using the same donor.

This limit is necessary, because all children from a single donor will be genetic half-siblings. The small chance that they might meet later in life and be unaware of the relationship raises health concerns about their potential offspring.

Because of the costs involved in screening, some programs ask prospective donors to commit, in advance, to donate eggs several times. Think carefully before agreeing. You do not know how the medications will affect you, how difficult the procedure will be, or how you will react to the possibility of creating genetic offspring.

Do not sign a consent form for more than one cycle of egg donation. Even if you do sign, no one can force you to make multiple donations. On the other hand, it is reasonable for a program or donor egg recipient to want to know if you would consider donating eggs more than once. A recipient may see you as an ideal match and wonder whether, if there is not a successful pregnancy, you would be willing to try again. Or, if a child is born, she may wonder if you would help her conceive that child's little brother or sister.

GLOSSARY

ART (assisted reproductive technology) – All treatments or procedures that involve surgically removing eggs from a woman's ovaries and combining the eggs with sperm to help a woman become pregnant.

Canceled cycle – An ART cycle in which ovarian stimulation was carried out but which was stopped before eggs were retrieved.

Egg – The female reproductive cell, also called an oocyte.

Egg retrieval – A procedure to collect the eggs contained in the ovarian follicles.

Embryo transfer – Placement of embryos into a woman's uterus through the cervix after in vitro fertilization.

Fertilization – The penetration of the egg by the sperm and the resulting combining of genetic material that develops into an embryo.

Follicle – A structure in the ovaries that contains a developing egg.

Gestation – The period of time from conception to birth.

In vitro fertilization (IVF) – An ART procedure that involves removing eggs from a woman's ovaries and fertilizing them outside her body. The resulting embryos are then transferred into the woman's uterus through the cervix.

Miscarriage – A pregnancy ending in the spontaneous loss of the embryo or fetus before 20 weeks of gestation.

Multifetal pregnancy reduction – A procedure used to decrease the number of fetuses a woman carries and improve the chances that the remaining fetuses will develop into healthy infants.

Oocyte – The female reproductive cell, also called an egg.

Ovarian stimulation – The use of drugs to stimulate the ovaries to develop follicles and eggs.

Sperm – The male reproductive cell.

Ultrasound – A technique used in ART for visualizing the follicles in the ovaries and the gestational sac or fetus in the uterus.

Source: CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health

**CHECKLIST:
BEFORE YOU GIVE CONSENT TO DONATE EGGS**

Be sure you carefully read the informed consent documents. Do not give your written consent to become an egg donor unless you have received acceptable answers to all of your questions:

- ___ What screening tests will be performed?
- ___ What are the pros and cons of genetic testing?
- ___ What procedures and medications will be part of your donation process?
- ___ Have they been thoroughly described?
- ___ What are the risks of any drugs, procedures and anesthesia?
- ___ What are the side effects?
- ___ What information about you will the program keep on file?
- ___ What are all the currently known ways that your eggs or resulting embryos might be used?
- ___ What information about you will the program give to the recipient?
- ___ What costs might you have to pay if you need treatment for complications?
- ___ At what point can you no longer change your mind about the donation?
- ___ What financial compensation will you receive for a completed cycle or one canceled before egg retrieval (for various possible reasons)?
- ___ Do you fully understand and agree with all conditions?

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ON LIFE AND THE LAW**

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EXHIBIT 35



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University of Colorado Denver

Egg Donor Applicant Information

Introduction

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Risks of IVF

Side Effects of Gonadotropins

Anesthesia for IVF Procedures

Introduction

This section of the website will provide an overview of what is involved with the process to become an oocyte (egg) donor. The first step is filling out an egg donor application. These applications are available by calling 720.848.1675 or click on the link **egg donor application (PDF)**, to get the application online. [PDF help] Please complete this application and mail it to our office at the Anschutz office address found below, attention: Sandy Hahn, RN.

Once our team receives the application, we will then review your responses and see if you qualify. Those applicants qualifying will be called to schedule appointments to be seen at our office. Those applicants not qualifying will be sent a letter with an explanation of why you have not been selected. After an initial consultation with one of our nurses, you will meet with the IVF physicians for an donor egg physical exam and one of our clinical psychologists for a psychological evaluation. If these evaluations go well then you will undergo blood testing, to test the quality of your eggs and to check that you are healthy. The test to check the quality of your eggs will involve taking medication for 5 days. If you pass all these tests you will be placed on the egg donor list for the recipient infertility couples to select you as a donor. Once you are selected we will call you by phone. The usual wait time to be selected is 2 months.

Once you are selected the entire donor cycle lasts approximately four to eight weeks. It is very important to note that during the last two weeks of the cycle you will not be able to go out of town. During these two weeks you will be required to make an office visit about every other day between the hours of 8:00 a.m. and 10:00 a.m. for an approximately one-half hour visit. During these times an ultrasound and a blood test will be performed. Additionally, you will need one day off work the day the oocyte retrieval is performed. If it is not possible for you to make these visits, please notify the staff immediately. Below is a summary of the procedure you will be involved with:

IVF refers to the creation of embryos by placing sperm and eggs in a test tube or culture dish in a laboratory setting. In order to perform this procedure, oocytes (eggs) must be obtained by stimulating your ovaries with fertility medications, "superovulating drugs," and then retrieving your oocytes from the ovaries by having you undergo a minor surgical procedure, with the use of anesthesia. The oocyte retrieval involves the passage of a needle through the thin posterior wall of the vagina into the ovary and aspirating the oocytes from the ovary. After collection of the oocytes, the sperm sample from the couple and your oocytes are prepared and then mixed together in the embryology laboratory in an incubator for the purpose of creating embryos. These embryos are allowed to grow in the incubator for an additional two to five days before being transferred. The transfer procedure uses a small tube placed through the cervix directly into the uterus of the woman receiving the oocyte donation with the hope that the embryos will implant in the uterus and result in a pregnancy. You will be the "donor" of the oocytes; the woman having the embryos placed into her uterus is referred to as the "recipient".

The purpose of "superovulating drugs" is to stimulate the ovaries to produce more than one egg. This process involves a series of blood tests (estradiol levels) and ovarian follicle measurements (ultrasounds) to assess individual needs for medication and to determine when the oocytes are ready for removal. Lupron or AntagonTM is given to prevent ovulation from occurring before the oocytes are removed. A combination of Metrodin, Follistim, Gonal-F, Repronex, Fertilinex (FSH), Pergonal, or Humegon (hMG) may be used. These medicines are only available in the form of injections. The injections should be given between 6:00 p.m. and 10:00 p.m. We will teach you how to mix and give injections. You will be asked to comply with the following restrictions during treatment:

1. **MEDICATIONS:** Do not take any medications except Tylenol, unless approved by the IVF doctor.
2. **SOCIAL HABITS:** Alcohol should be minimized for three months prior to treatment and at all times during the IVF cycle. Cigarette smoking should be stopped three months prior to the IVF cycle. Any illegal drug use should be stopped immediately.
3. **INTERCOURSE:** In general, you will be asked to refrain from intercourse during the donor oocyte cycle until 16 days after the oocyte retrieval. You will be extremely fertile until your cycle is complete. Therefore to avoid pregnancy, you must avoid intercourse until you have the first menses after your oocyte retrieval.
4. **ACTIVITY:** Your normal routine may be continued unless enlargement of your ovaries produces discomfort.
5. **VAGINAL AND GENITAL INFECTIONS:** Please report any history of genital herpes exposure with or without documented history of herpes lesions. You must report any pre-herpes symptoms, active lesions, or healing herpes lesions. Please report any abnormal vaginal discharge in the three months prior and during your IVF cycle. Any infection (including a vaginal yeast infection) can cause infections in the embryos or pelvis, so they will need to be treated prior to oocyte retrieval.
6. **EXERCISE:** Do not begin any new exercise, sport, or marathon training within three months prior to your IVF cycle. Please minimize or stop vigorous exercise for one month prior to the retrieval.

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Advanced Reproductive Medicine**

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The egg donation process consists of two phases. In the first phase, ovarian hyperstimulation, donors receive a series of hormonal drugs which cause the ovaries to produce multiple mature eggs during one menstrual cycle. During the second phase, egg retrieval, mature eggs are removed from the donor through a surgical procedure called transvaginal ultrasound aspiration. Egg donors should expect to spend around 60 hours for screening, testing, and medical appointments throughout the course of the procedure.

Ovarian Hyperstimulation

Women generally receive three classes of drugs during the ovarian hyperstimulation phase of donation. Prior to beginning the three-drug regimen, some donors may also take birth control pills in order to regulate their menstrual cycles.

- **Gonadotropin-Releasing Hormone Agonist Analogues**

These first stage of the hormonal drug regimen utilizes a class of drugs termed gonadotropin-releasing hormone agonist analogues. These drugs are used to suppress the release of luteinizing hormone (LH) by the pituitary gland, which normally triggers eggs to mature within the body. This creates an "artificial menopause" in donors. Physicians can then control the timing of egg maturation and ovulation through the administration of other medications.

These drugs are generally administered through daily subcutaneous injections over the span of the stimulation cycle, and donors are encouraged to rotate injection sites to limit bruising. As an alternative to multiple injections, some clinics may prescribe a daily nasal spray or administer a single injection of Depot Lupron at the beginning of treatment.

Commercial forms of Gonadotropin-Releasing Hormone Agonist Analogues include:

- Buserelin/Suprefact
- Lupron
- Goserelin/Zoladex
- Nafarelin
- Triptorelin
- Synarel
- Prostag

- **Follicle Stimulating Hormone or Human Menopausal Gonadotropin**

After hormone levels have been suppressed by the first class of drugs, donors then begin a daily injections of either follicle stimulating hormone (FSH) or human menopausal gonadotropin (hMG). This will encourage the development of multiple egg follicles, allowing the physician to retrieve several mature eggs at one time.

Because of elevated fertility at this point, donors in many programs are required to abstain from sexual intercourse to protect against unwanted pregnancy. While donors are taking these medications, physicians will periodically measure for the maturation of eggs through pelvic ultrasounds and blood tests. Dosage levels of FSH or hMG may be adjusted to minimize side effects and optimize the number of eggs available for harvest. During the last days of hyperstimulation, donors will undergo daily ultrasounds and blood tests.

Commercial forms of FSH or hMG include:

- o Gonaf/f
- o Pergonol
- o Humegon
- o Menagon
- o Urofollitropin/Metrodin
- o Clomid tablets

• Human Chorionic Gonadotropin

Once tests indicate that eggs have matured, ovulation is triggered through a single injection of human chorionic gonadotropin. Egg retrieval occurs 34-36 hours after this injection.

Commercial forms of Human Chorionic Gonadotropin include:

- o Pregnyl
- o APL
- o Oxidrel

Side Effects of Ovarian Hyperstimulation

While allergic reactions to fertility medications are unlikely, donors commonly experience abdominal swelling, tension and pressure in the ovarian area, mood swings, and bruising at injection sites as a result of fertility drugs. Temporary menopause-like symptoms, including vaginal dryness and hot flashes, may result. In treatment centers not requiring donors to abstain from sexual intercourse, unintentional pregnancy is another common complication. In one study of 110 donors, 7 percent experienced accidental pregnancy between donation cycles due to enhanced ovulation.

A less frequently occurring risk is ovarian hyperstimulation syndrome (OHSS), a serious complication marked by chest and abdominal fluid buildup and cystic enlargement of the ovaries that can cause permanent injury and even death. According to one study, severe OHSS affects between 1 and 10 percent of donors depending on the drug regimen used, although other studies show a lower incidence of the condition. Patients with OHSS may experience dehydration, blood clotting disorders, and kidney damage.

Less than one percent of the time, drugs can also cause adnexal torsion, a condition that results when a stimulated ovary twists on itself and cuts off its blood supply. Surgery is required to untwist and in some cases to remove the ovary. Additionally, some studies suggest that clomiphene, a drug sometimes used during hyperstimulation, may increase a woman's chance of developing ovarian cancer. However, this risk applies mostly to women who take the drug for a year or more. A few case reports have shown that the drug Lupron can aggravate existing tumors of the pituitary gland and cause strokes.

While serious complications are rare, a majority of donors will report pain and mild side effects from the procedure. In a recent survey of 61 egg donors, 64 percent responded that the physical side effects of fertility drugs, injections, and retrieval were a negative aspect of donation.

» [Click here to see a sample Treatment Calendar for donors](#)

Egg Retrieval

Eggs are retrieved from the donor through transvaginal ultrasound aspiration, a surgical procedure performed under conscious sedation. (See figure below). Using a tube attached to an ultrasound probe, a physician guides a suctioning needle into each ovary and removes mature oocytes from the follicles. A medication such as oral promethazine may be used to prevent nausea during the procedure. Following egg retrieval, donors generally remain in the clinic for 1-2 hours and then return home for further recovery. An antibiotic such as oral doxycycline will be prescribed to prevent infection, and donors should undergo a follow-up exam and ultrasound one week after the retrieval.

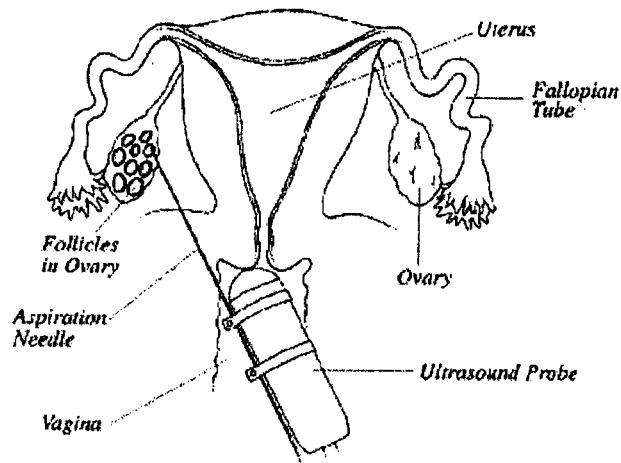


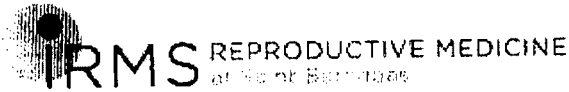
Fig.1 Egg retrieval through transvaginal ultrasound aspiration.
Courtesy of ASRM.

Side Effects of Egg Retrieval

Because egg retrieval involves surgery, donors may occasionally suffer structural damage to organs in close proximity to the ovaries. Major injury to the bladder, bowel, uterus, blood vessels or other pelvic structures occurs in approximately 1 in 500 to 1000 surgeries. Though the procedure is performed under sedation or mild anesthesia, egg retrieval can cause mild to moderate discomfort. Surgical risks include acute ovarian trauma, infection, infertility, vaginal bleeding, and lacerations. Additionally, anesthetic complications may occur, although they are rare in healthy women. In one study of 674 women who underwent egg retrieval, 1.5 percent required hospitalization due to complications occurring during or after surgery.

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EGG DONATION

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Step by Step Guide

Most couples never think they will have trouble starting a family; yet one in seven couples of childbearing age will experience the pain of infertility. This can be a devastating experience.

Now, with the assistance of today's revolutionary fertility treatments, couples have a better chance than ever of becoming pregnant. IRMS for Reproductive Medicine reports pregnancy rates that are among the highest in the nation. Our medical staff includes internationally renowned specialists in infertility treatment, as well as distinguished embryologists and biologists who pioneered many of the assisted reproductive techniques in use today.

Initial Consultation and Screening

All donors undergo a **screening** to determine whether or not egg donation is appropriate for them. This includes laboratory work to study the individual's level of day 3 FSH, an indicator of whether or not she would be a suitable candidate. Other laboratory testing, such as HIV, blood type and other bloodwork, is performed. This is followed by a twopart psychological screening that includes a Personality Index Test and interviews with a nurse and mental health professional. Finally, a physician performs a medical examination.

There are two types of egg donors, known and anonymous. The **known donor** is usually a relative or friend of the recipient. The **anonymous donor** does not meet the recipient. Anonymous donors provide recipients with a medical history, educational background and psychological profile, all arranged through IRMS. After retrieval, the anonymous donor is not told whether or not the donation of her eggs resulted in a pregnancy.

Although currently anonymous, these donors should be aware that in the future the legal system could reverse their anonymity. IRMS takes multiple precautions to protect the privacy of the donors.

Egg Donation at IRMS:

Step One: Matching Donor and Recipients

Each egg donor is notified when a match has been made with a potential recipient. At this time, the nurse and the egg donor reserve a period of time for the procedure, and IRMS orders injectable medications. The egg donor now begins a class and receives detailed instructions on how to properly administer the injectables. The dose of the medication, the time it is administered and the duration of treatment vary from person to person.

Step Two: Creating the Optimum Cycle

The egg donor calls the nurse as soon as her menstruation occurs. Then, with the help of birth control pills, both the donor and recipient cycles are synchronized. In order to maximize egg donation, the egg donor undergoes stimulation of her ovaries so that multiple eggs may be harvested. More than one egg is needed because not every egg will be healthy and not every healthy egg will produce a pregnancy.

Due to concerns regarding passing infectious diseases through the eggs to the recipient, the FDA now requires that we repeat some of the testing that we do at your initial evaluation around the time we start your medications. This testing will consist of a repeat physical exam, a questionnaire, blood testing and cervical cultures. If any of this testing is abnormal, the cycle may be cancelled. To reduce the risk of failing this testing, once you have applied for the donor program, please check with the nurse before traveling outside of the country. Please also avoid getting tattoos or piercings. Donation must be postponed for 1 year after obtaining a tattoo or piercing.

The drugs used will depend upon the physician's assessment of the donor, the type and dose of medications she needs. There are suppression medications that are taken to prevent premature release of the egg. One of these is Lupron, an injectable medication, which is overlapped with the birth control pills. Another suppression medication is a GnRH antagonist (brand names Gonal-F and Follistim), which is also an injectable medication. Gonadotropins, which stimulate multiple egg production are injected by the egg donor at home and require daily to twice daily administration. They are injected for an average of 6 to 12 days per cycle. Despite the fact that these are very powerful medications, they are usually well tolerated. Most people experience some mild side effects, such as fatigue, bloating and mild cramping. Any questions or concerns about symptoms you are experiencing should be reviewed with your nurse.

Of Note:

- During the stimulation cycle, IRMS recommends abstinence from intercourse, as the donor is especially fertile while on these medications. If intercourse takes place, the use of condoms and spermicides together is strongly recommended to prevent pregnancy and sexually transmitted diseases.
- It is important to inform the Ovum Donation Team about any medications (prescription and over-the-counter), diets, nutritional supplements and herbal remedies you are taking. In general, during the donation cycle, any non-essential medications should be stopped. Please review this with the nurse

prior to making any changes on your own.

- Tattooing and piercing should not be done within 1 year of egg donation to prevent the risk of transmission of hepatitis and HIV. of transmission of hepatitis and HIV.

Step Three: Monitoring the Cycle

Once the stimulation cycle has started, the egg donor comes to either IRMS in Livingston or Hoboken (or the designated satellite), in the morning every 1-3 days to be evaluated for follicle maturation. This is determined by daily blood levels and ultrasound, which are performed between 6:30 and 8:00a.m.in Livingston and 7:00 to 9:00 am. in Hoboken. Monitoring is performed in the morning so that the results are available by the afternoon for review by the physician. The nurse will call you at that time to make any necessary medication adjustments and to let you know when to return for more testing. Sometimes donors have other commitments that may interfere with the cycle, and it is important to inform the team fully about this. Not everyone responds the same way to the medications and the cycle schedule does not always go as planned. Once the stimulation starts, the donor must be available for monitoring every day, if necessary, until the retrieval takes place. It is usually two weeks from the beginning to the retrieval, but may take several days longer, or may occur earlier than planned.

Step Four: The hCG Injection

At an exact time determined by the physician, an injection of human Chorionic Gonadotropin (hCG) is given to bring the eggs to final maturity. This injection is performed at IRMS by one of our RN's.

The timing of the hCG injection is critical to the success of the cycle. If it is given too early or too late, it could significantly lower the chances for obtaining healthy eggs. A nurse or physician is on call 24 hours a day, 7 days a week and 365 days a year through our main number: (973) 322-8286. If it is after hours, please ask the answering service to page the on-call nurse or doctor.

Retrieving the Eggs: The Final Step

The night before the egg retrieval, the donor should neither eat nor drink because the procedure involves the use of intravenous anesthesia. An empty stomach increases the safety of the procedure. A full stomach may result in the cancellation of the egg retrieval. On the day of the event, each patient must be accompanied by a person who can drive her home and stay with her for 24 hours after the procedure. If a companion is not present, the procedure may be cancelled. At 34-37 hours after the administration of the hCG injection, eggs are harvested from the donor. This procedure is performed at IRMS's operating facility at the Atkins-Kent Building, across the street from the Medical Center.

Retrieval involves aspirating the fluid in the ovarian follicles with a special needle to obtain the eggs. This minor procedure, performed with the patient under anesthesia, is done in the Same Day Surgery Center by a physician using ultrasound visualization and does not require an incision.

Egg donors can return home a few hours after the egg retrieval. Safety regulations restrict the patient from driving or operating machinery after sedation. The donor should rest that day and avoid intercourse or aerobic activity. It is important the donor have a companion for the first 24 hours after the retrieval. Although complications are unlikely, the most common time for serious complications to occur is during the 24 hours after retrieval.

Of note:

Intercourse should be avoided to prevent unwanted pregnancy in the donor and infection in the donor after retrieval.

Aftercare for the Egg Donor

To make sure that she recovers completely from the egg retrieval, each donor should follow a few simple guidelines.

1. Check in with IRMS within 24-48 hours after egg donation.
2. Take an antibiotic the day of the retrieval and finish the entire four-day dose. Antibiotics protect against any infection.
3. Get plenty of rest the day of the egg retrieval.
4. Resume your regular diet, but supplement it with plenty of extra fluids.
5. Be aware that you will be extremely fertile in the time before your next menstruation period and unprotected intercourse could result in pregnancy.
6. Avoid aerobic or high impact activity.
7. Avoid intercourse as the ovaries are fragile at this point and excessive movement of the ovaries could increase the risk for bleeding and twisting of the ovaries.
8. Weigh yourself every day and call IRMS if you notice more than a 2-pound weight gain in one day.
9. Monitor your urine output. If it is significantly less than the amount you are drinking or the urine becomes dark, please contact IRMS and speak with a nurse.
10. Please call a nurse at IRMS should any pain, fever, nausea, vomiting, or bleeding occur.
11. Make sure that you have a companion stay with you for the first 24 hours after retrieval. This is a requirement for your safety.
12. Call IRMS immediately should any complications occur.

Follow Up/Compensation

Donors can expect to begin menstruation approximately 14 days after egg retrieval. At this time, the donor should call the nurse to schedule a Day Three Ultrasound appointment at IRMS. This final step ensures that the ovaries have returned to normal size.

At this last appointment, all donors who have completed the retrieval process receive a compensation check for \$8,000.

Donating Again

After the retrieval process, some egg donors wish to donate more eggs. Many donors can donate more than one time. These issues should be discussed with a nurse at IRMS.

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UCSF Medical Center

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FAQ: Common Questions for Egg Donors

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Who are the recipients?

Couples generally choose to use donor eggs because they're unable to conceive a child with the female partner's own eggs. There are many reasons that a woman may not be able to conceive with her own eggs, including older age, early menopause, poor-quality eggs or previous cancer treatments that damaged the ovaries. Frequently, recipients have already been through extensive fertility treatments without success.

Egg recipients can be couples or single women or men. At UCSF, all recipients for our egg donor program are UCSF patients.

Why should I choose the UCSF Ovum Donor Program?

The UCSF Egg Donor Program is part of the UCSF Center for Reproductive Health. Our team has expertise from some of the top programs in the country, and all of our physicians are board certified in both obstetrics and gynecology and reproductive endocrinology and infertility. We have been helping patients become parents using donated eggs since 1991 and were one of the first programs in the Bay Area to do so.

Because the UCSF Egg Donor Program only provides eggs to UCSF patients, you will receive all your care in one setting. Egg donor agencies may send you to donate at various locations, all of which may have different processes.

If I'm interested in participating, how do I get started?

You may download an application, fill it out and email it to eggdonorprogram@ucsfmedctr.org. Once the application is returned, we can consider you for the next steps of the screening process.

Alternatively, you may call our egg donor coordinator at (415) 353-9251 or email us at eggdonorprogram@ucsfmedctr.org.

What's involved in the screening process?

You will be asked to complete a detailed questionnaire about your background and your medical, family and personal history. After that is complete and has been reviewed by our staff, we will call to arrange screening appointments with our psychologist and genetic counselor. The last step in the screening process is a physical examination with a doctor and laboratory tests.

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 California

What's the compensation?

We offer ovum donors \$8,000 for their time, travel and efforts, once they have completed an ovum donation cycle. The medical screening you will receive before donating is performed at no cost to you, and you may request results of all your medical tests for your own records or to give to your doctor.

Many egg donors report the positive emotional impact as an additional form of "compensation." Knowing you've helped complete a family can be very rewarding.

Can you describe the whole process?

For a detailed description, please see [Egg Donation Process for Donors](#).

How much time is involved?

The screening process generally takes a few weeks to complete. You will speak to the Egg Donor Program coordinator by phone and come into the office for a few short visits at our Mount Zion location. Once you're chosen as an egg donor, a cycle takes approximately four weeks.

During a two-week period, you'll come to the clinic about seven to 10 times for ultrasound monitoring and blood tests. These appointments generally require a 15- to 30-minute visit in the morning. The day that you are scheduled for the egg retrieval, you'll be at our clinic for a large portion of the day. Most donors are able to continue to work or go to school during the process.

Will I need to give myself shots?

Yes. The shots are done at home. You can do them yourself, or have a friend or family member help you. We will teach you how to mix and administer your medication in our office.

Are there possible side effects and risks?

As with any medical procedure, there are possible side effects and risks. Many women feel very minor or no discomfort during the donation cycle. Others have varying symptoms that typically resolve after the egg retrieval procedure. Some donors may feel bloating, pressure, abdominal pain and swelling, breast tenderness and moodiness from the hormone medications, which will go away by the next menstrual period. Severe side effects are rare and will be discussed with you in detail by a doctor before you join the program.

- **Injection side effects and risks** — The blood tests and hormone injections are usually well tolerated. However, some women

experience pain, redness or minor bruising at the injection site.

Allergic reactions are rare.

- **Medication side effects and risks** — There is a small risk of ovarian hyperstimulation syndrome (OHSS) developing during an egg donation cycle. OHSS generally occurs after the egg retrieval and involves enlargement of the ovaries, significant increases in fluid retention within the abdomen and concentration of the blood within the blood vessels.

In its more mild form, OHSS can be uncomfortable but resolves within several days. The severe form, which occurs in about 1 percent of donor cycles, may require hospitalization for monitoring. While the condition is serious, it usually lasts no more than one week.

- **Procedure side effects and risks** — The egg retrieval procedure is guided by transvaginal ultrasound. The risk of serious complications from this procedure is rare — about 1 in 1,000. Serious complications involve bleeding that requires observation in the hospital, blood transfusion, or both, as well as damage to internal organs and infection.
- **Other side effects and risks** — To date, evidence doesn't suggest any increased risk of breast or ovarian cancer from serving as an egg donor. There is no evidence of increased risk of infertility.

Are there any restrictions during the process?

You can get pregnant during the egg donation process, so we ask that you abstain from intercourse during the process.

Your ovaries will become enlarged during the egg donation process. We ask you to refrain from high-impact activities such as running, mountain biking and jumping until several weeks after the egg retrieval. After approximately one month, your ovaries will return to their normal size.

Can I become pregnant during treatment?

Yes! It's very important to avoid intercourse from the time you start the hormone medication until three weeks after your egg retrieval. This will prevent an unwanted pregnancy and ensure the cycle goes as planned.

Will it impact my fertility or deplete my eggs?

No. The procedure itself doesn't have any impact on your future ability to have children. Women are born with about 2 million eggs. Each month, a group of eggs begin the maturation process, but the body selects only one egg each cycle to ovulate, while the rest are absorbed by the body. Fertility medications "rescue" some of these excess eggs that the body would have ordinarily discarded.

Can I still work or go to school?

Although the egg donation process requires you to adhere strictly to your medication and appointment schedule, most women are able to continue with work and school without difficulty.

However, you must take the medication as instructed, and on time. You must be on time for all monitoring appointments, and you must arrange for transportation to and from the egg retrieval. This means you will need to make your egg donor cycle a top priority during the few weeks that it occurs, and you may have to reschedule other events, classes or work times as necessary.

What are my responsibilities if I agree to become a donor?

The responsibilities of ovum donors are:

- Be truthful in all portions of the donor screening process.
- Follow the doctors' orders during the treatment cycle.
- Adhere strictly to your medication and appointment schedule. You must take the medication as instructed and on time, and arrive for all monitoring appointments on time. This means you must make your egg donor cycle a top priority during the few weeks that it occurs.
- Arrange for transportation to and from the egg retrieval procedure.
- Abstain from sex from the time you start the hormone medication until three weeks after your egg retrieval, to prevent an unwanted pregnancy and make sure the cycle proceeds as planned.

Do I have legal responsibilities to any child born?

When you agree to donate your eggs, you are giving up all rights and responsibilities associated with the eggs and any child born as a result of them.

Will the recipients know me or meet me?

Most egg donor arrangements are anonymous, meaning you won't know the recipients and they won't know you. Information about you is shared with the recipients in a non-identifying manner. For example, we share the following information: your blood type, ethnic background of your mother and father, height, weight, body build, eye color, hair color and texture, years of education, occupation, special interests and family medical history. Pictures you give us will also be shared with potential recipients. We will not share your last name, address, telephone number or email address.

We are committed to creating egg donation arrangements that fit the personal needs of both donor and recipients. Some donors and recipients are interested in meeting each other and we support that process, if all parties are willing. On your application, you will indicate whether you're willing to meet the recipients, and whether you would be willing to meet their child when the child is an adult.

Can I donate more than once?

Yes. If all goes well with your first egg donation cycle, we would be happy to have you come back and donate again. Repeat donation may take less of your time, because you will have already completed the initial screening process.

For your safety, ovum donors can donate no more than six times. This guideline was established by the American Society for Reproductive Medicine.

Reviewed by health care specialists at UCSF Medical Center.
Last updated February 24, 2011

This information is for educational purposes only and is not intended to replace the advice of your doctor or health care provider. We encourage you to discuss with your doctor any questions or concerns you may have.

EXHIBIT 36

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENCHEM
GROSSBAUM, her spouse,
individually, as guardians ad
litem of the infant, ROSIE
GROSSBAUM,

Plaintiffs,

v.

GENESIS GENETICS INSTITUTE,
L.L.C., of the State of Michigan,
MARK R. HUGHES, M.D., NEW YORK
UNIVERSITY SCHOOL OF MEDICINE and
NEW YORK UNIVERSITY HOSPITALS
CENTER, both corporations in the
State of New York, ABC
CORPORATIONS 1-10 and JOHN DOE
1-10,

DEPOSITION OF:

FREDERICK LICCIARDI

T R A N S C R I P T of the stenographic notes of
the proceedings in the above-titled matter, as taken by
PHILIP A. FISHMAN, a Certified Shorthand Reporter and
Notary Public of the State of New Jersey, held at the
offices of Dr. Frederick Licciardi, 660 First Avenue,
New York, New York, on Wednesday, March 11, 2009,
commencing at 3:00 in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
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14th Floor
Morristown, New Jersey 07960
(973)285-5331 - FAX (732)605-9391

Licciardi - Direct - Stein

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1 testing was done, that that would be a matter of serious
2 concern to the department?

3 A. Yes.

4 Q. And so is it fair to say that would have
5 generated then some intradepartmental discussion?

6 A. Most likely.

7 Q. When you found out that this baby had cystic
8 fibrosis, did that generate some discussion in the
9 department?

10 A. Yes.

11 Q. And did that discussion relate to the question of
12 whether or not something was -- a mistake was made at
13 Genesis Genetics?

14 MR. LEUCHTMAN: I am going to object.

15 I am not sure what the statute is in New
16 Jersey, or if New Jersey law controls this case,
17 but, generally speaking, morbidity and mortality
18 conferences are exempt from discovery and
19 certainly exempt from being testified to, so I
20 maintain if there is no problem with this, a
21 continuing objection to this line of questioning.

22 MR. STEIN: Okay.

23 Q. Can you answer the question?

24 A. Repeat the question, please.

25 (Whereupon, the court reporter reads as

EXHIBIT 37

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Treating Infertility at NYUFC

The NYUFC Team

Jamie A. Grifo, MD, PhD

Dr. Grifo's Publications

Alan S. Berkeley, MD

Nicole Noyes, MD

Frederick Licciardi, MD

M. Elizabeth Fino, MD

David L. Keefe, MD

Lisa M. Kump-Checchio, MD

Wellness Program
Practitioners

Fellows

Administrative Staff

Laboratory Staff and
NursingOocyte Donation Support
Staff[Pregnancy Rates](#)[Financial Information](#)[Medical Breakthroughs](#)[Physician Referrals](#)[REI Fellowship Program](#)[NYS Infertility Project](#)[Satellite Offices](#)

Jamie A. Grifo, MD, PhD

Current patients and those interested in seeing Dr. Grifo for a new consultation should call (212) 263-7978.

Since August 1995, Dr. Grifo has been the Director of the [Division of Reproductive Endocrinology](#) at the NYU School of Medicine, and also holds the faculty appointment of Professor of Obstetrics and Gynecology at the NYU School of Medicine. He received his MD and PhD degrees at Case Western Reserve Medical School and completed his residency at Cornell University Medical Center. After completing a Fellowship in Reproductive Endocrinology at Yale University, he returned to Cornell and established a medical practice specializing in the treatment of infertility in the Division of Reproductive Endocrinology. He is Board Certified in Obstetrics and Gynecology and Reproductive Endocrinology, as well as being certified by the Accreditation Council for Gynecologic Endoscopy.



A member of the [American Society for Reproductive Medicine \(ASRM\)](#) since 1989, Dr. Grifo has served on the Ethics Committee and is currently the president of the [Society for Assisted Reproductive Technologies \(SART\)](#). He chaired the committee which developed an innovative computer program to collect IVF facility data in a more efficient and cost-effective manner. He has worked closely with the CDC on this project.

His scientific interests are focused in the area of pre-implantation genetic diagnosis and his team had the first successful delivery in the United States from the embryo biopsy procedure. Subsequently, there have been more than 200 babies born by PGD worldwide thus far. He has served as an ad hoc reviewer for the [New England Journal of Medicine \(NEJM\)](#), [Journal of the American Medical Association \(JAMA\)](#), [Human Reproduction](#), [Obstetrics and Gynecology](#), and [Fertility and Sterility](#). In 1994, Dr. Grifo's research paper, "Healthy Deliveries from Biopsied Human Embryos," was awarded the SART prize at the annual ASRM meeting. He has over 130 publications in peer reviewed journals, as well as many book chapters.

His research focuses on the use of Germinal Vesicle Transfer as an alternative to Egg Donation, Egg Freezing, PGD and Stem Cells. When asked to list his professional accomplishments, Dr. Grifo is most enthusiastic about the success of the process of pre-implantation genetic diagnosis where basic science truly can be utilized to affect the quality of life for so many people. His participation in the success of the IVF program at NYU - most recently the construction of the premier American state-of-the-art facility and the ability to collaborate with a research team that shares his enthusiasm for the advancement of clinical applications of basic science.

[View Dr. Grifo's Website](#)[View recent publications by Dr. Grifo](#)